IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CUBIST PHARMACEUTICALS, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 12-367-GMS
HOSPIRA, INC.,	)	
Defendant.	)	

DEFENDANT HOSPIRA, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS TO PLAINTIFF CUBIST PHARMACEUTICALS, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Defendant HOSPIRA, INC. hereby answers the Complaint filed by CUBIST PHARMACEUTICALS, INC. as follows:

AS TO THE NATURE OF ACTION

1. Hospira admits that the Complaint purports to state an action under the patent laws of the United States. Hospira further admits that Hospira filed an Abbreviated New Drug Application No. 202857 ("ANDA No. 202857") with the FDA seeking approval to manufacture and sell Daptomycin for Injection, 500 mg/ vial ("the Hospira ANDA Product"), a generic version of CUBICIN®, before the expiration of U.S. Patent Nos. 6,468,967 ("the '967 patent"), 6,852,689 ("the '689 patent"), RE39,071 ("the RE'071 patent"), and 8,058,238 ("the '238 patent"). Hospira denies the remaining allegations in paragraph 1 of the Complaint.

AS TO THE PARTIES

2. Hospira lacks knowledge or information sufficient to admit or deny the allegations of paragraph 2 of the Complaint.

3. Hospira admits that it is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois.

4. Hospira admits that it sells various generic drug products in the United States, including in Delaware. The remaining allegations contained in paragraph 4 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the remaining allegations.

AS TO JURISDICTION AND VENUE

5. The allegations contained in paragraph 5 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the Court has subject matter jurisdiction over this matter under 28 U.S.C. §§ 1331 and 1338(a). Hospira denies the remaining allegations in paragraph 5 of the Complaint.

6. The allegations contained in paragraph 6 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits, for purposes of this action only, that venue is proper in this district under 28 U.S.C. §§ 1391 and 1400(b).

7. The allegations contained in paragraph 7 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that it is incorporated under Delaware law and that it markets and sells drug products in the United States, including in Delaware. Hospira further admits that the Court has personal jurisdiction over Hospira in this action. Hospira denies the remaining allegations of paragraph 7 of the Complaint.

AS TO THE BACKGROUND

8. Hospira admits that CUBICIN® is FDA approved and that, according to its label, is a lipopeptide antibacterial indicated for the treatment of (1) complicated skin and skin structure infections; (2) *Staphylococcus aureus* bloodstream infections, including those with right-sided infective endocarditis. Hospira denies the remaining allegations in paragraph 8 of the Complaint.

9. Hospira admits the allegations in paragraph 9 of the Complaint.

10. Hospira admits that the '967 patent states on its face that it is entitled "Methods for Administration of Antibiotics" and further states that it was issued on October 22, 2002 and is assigned to Cubist. Hospira admits that the '967 patent is listed in the FDA Orange Book as expiring on September 24, 2019. Hospira further admits that what appears to be a copy of the '967 patent was attached to the Complaint as Exhibit A. Hospira denies the remaining allegations of paragraph 10 of the Complaint.

11. Hospira admits that the '689 patent states on its face that it is entitled "Methods for Administration of Antibiotics" and further states that it was issued on February 8, 2005 and is assigned to Cubist. Hospira admits that the '689 patent is listed in the FDA Orange Book as expiring on September 24, 2019. Hospira further admits that what appears to be a copy of the '689 patent was attached to the Complaint as Exhibit B. Hospira denies the remaining allegations of paragraph 11 of the Complaint.

12. Hospira admits that the RE'071 patent states on its face that it is entitled "Anhydro-and Isomer-A-21978C Cyclic Peptides" and further states that it was issued on April 18, 2006 and that an assignment was recorded in the PTO on April 23, 2007 assigning the RE'071 patent to Cubist. Hospira admits that the RE'071 patent is listed in the FDA Orange

Book as expiring on June 15, 2016. Hospira further admits that what appears to be a copy of the RE'071 patent was attached to the Complaint as Exhibit C. Hospira denies the remaining allegations of paragraph 12 of the Complaint.

13. Hospira admits that the '238 patent states on its face that it is entitled "High Purity Lipopeptides" and further states that it was issued on November 15, 2011 and is assigned to Cubist. Hospira further admits that what appears to be a copy of the '238 patent was attached to the Complaint as Exhibit D. Hospira denies the remaining allegations of paragraph 13 of the Complaint.

14. Hospira admits that the '967, '689, RE'071 and '238 patents have been listed in the FDA Orange Book in connection with CUBICIN®. The remaining allegations contained in paragraph 14 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the remaining allegations.

15. Hospira admits the allegations of paragraph 15 of the Complaint.

16. Hospira admits the allegations of paragraph 16 of the Complaint.

17. Hospira admits that this action appears to have been commenced within forty-five days of Cubist's receipt of Hospira's Notice Letter.

AS TO COUNT I:

INFRINGEMENT OF U.S. PATENT NO. 6,468,967

18. In response to the allegations contained in paragraph 18 of the Complaint, Hospira realleges its responses to paragraphs 1-17 as if fully set forth herein.

19. The allegations contained in paragraph 19 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies that all future uses of the Hospira ANDA Product in accord with its proposed

labeling would necessarily be covered by at least one claim of the '967 patent, given that the claims have not yet been construed, and further denies that any claims that might cover such future uses are valid and enforceable.

20. Hospira admits the allegations of paragraph 20 of the Complaint.

21. The allegations contained in paragraph 21 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the submission of Hospira's ANDA with a paragraph IV certification to the '967 patent is considered a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) for purposes of creating a case or controversy between the parties so that the Court has jurisdiction over this matter. Hospira denies the remaining allegations of paragraph 21 of the Complaint.

22. Hospira denies the allegations of paragraph 22 of the Complaint.

23. Hospira denies the allegations of paragraph 23 of the Complaint.

24. Hospira avers that the decision on whether to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will depend on the facts and circumstances existing at the time it receives final FDA approval of ANDA No. 202857. Accordingly, and as of the date of this Answer, Hospira denies the allegations of paragraph 24 of the Complaint.

25. Hospira denies the allegations of paragraph 25 of the Complaint.

26. Hospira denies the allegations of paragraph 26 of the Complaint.

27. Hospira denies the allegations of paragraph 27 of the Complaint.

28. Hospira denies the allegations of paragraph 28 of the Complaint.

29. Hospira denies the allegations of paragraph 29 of the Complaint.

AS TO COUNT II:

INFRINGEMENT OF U.S. PATENT NO. 6,852,689

30. In response to the allegations contained in paragraph 30 of the Complaint, Hospira realleges its responses to paragraphs 1-29 as if fully set forth herein.

31. The allegations contained in paragraph 31 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies that all future uses of the Hospira ANDA Product in accord with its proposed labeling would necessarily be covered by at least one claim of the '689 patent, given that the claims have not yet been construed, and further denies that any claims that might cover such future uses are valid and enforceable.

32. Hospira admits that it had knowledge of the '689 patent when it submitted its ANDA to the FDA.

33. The allegations contained in paragraph 33 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the submission of Hospira's ANDA with a paragraph IV certification to the '689 patent is considered a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) for purposes of creating a case or controversy between the parties so that the Court has jurisdiction over this matter. Hospira denies the remaining allegations of paragraph 33 of the Complaint.

34. Hospira denies the allegations of paragraph 34 of the Complaint.

35. Hospira denies the allegations of paragraph 35 of the Complaint.

36. Hospira avers that the decision on whether to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will depend on the facts and circumstances existing at the time it receives final FDA approval of ANDA No.

202857. Accordingly, and as of the date of this Answer, Hospira denies the allegations of paragraph 36 of the Complaint.

37. Hospira denies the allegations of paragraph 37 of the Complaint.

38. Hospira denies the allegations of paragraph 38 of the Complaint.

39. Hospira denies the allegations of paragraph 39 of the Complaint.

40. Hospira denies the allegations of paragraph 40 of the Complaint.

41. Hospira denies the allegations of paragraph 41 of the Complaint.

AS TO COUNT III:

INFRINGEMENT OF U.S. PATENT NO. RE39,071

42. In response to the allegations contained in paragraph 42 of the Complaint, Hospira realleges its responses to paragraphs 1-41 as if fully set forth herein.

43. The allegations contained in paragraph 43 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the allegations of paragraph 43 of the Complaint.

44. The allegations contained in paragraph 44 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the submission of Hospira's ANDA with a paragraph IV certification to the '071 patent is considered a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) for purposes of creating a case or controversy between the parties so that the Court has jurisdiction over this matter. Hospira denies the remaining allegations of paragraph 44 of the Complaint.

45. Hospira denies the allegations of paragraph 45 of the Complaint.

46. Hospira avers that the decision on whether to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will depend on the

facts and circumstances existing at the time it receives final FDA approval of ANDA No. 202857. Accordingly, and as of the date of this Answer, Hospira denies the allegations of paragraph 46 of the Complaint.

47. Hospira denies the allegations of paragraph 47 of the Complaint.

48. Hospira denies the allegations of paragraph 48 of the Complaint.

AS TO COUNT IV:

INFRINGEMENT OF U.S. PATENT NO. 8,058,238

49. In response to the allegations contained in paragraph 49 of the Complaint, Hospira realleges its responses to paragraphs 1-48 as if fully set forth herein.

50. The allegations contained in paragraph 50 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira denies the allegations of paragraph 50 of the Complaint.

51. The allegations contained in paragraph 51 state legal conclusions to which no responsive pleading is required. To the extent a responsive pleading is deemed to be required, Hospira admits that the submission of Hospira's ANDA with a paragraph IV certification to the '238 patent is considered a technical act of infringement under 35 U.S.C. § 271(e)(2)(A) for purposes of creating a case or controversy between the parties so that the Court has jurisdiction over this matter. Hospira denies the remaining allegations of paragraph 51 of the Complaint.

52. Hospira denies the allegations of paragraph 52 of the Complaint.

53. Hospira avers that the decision on whether to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product will depend on the facts and circumstances existing at the time it receives final FDA approval of ANDA No.

202857. Accordingly, and as of the date of this Answer, Hospira denies the allegations of paragraph 53 of the Complaint.

54. Hospira denies the allegations of paragraph 54 of the Complaint.

55. Hospira denies the allegations of paragraph 55 of the Complaint.

HOSPIRA, INC.'S ANSWER TO THE PRAYER FOR RELIEF

Hospira denies that Plaintiff Cubist is entitled to the judgment and relief prayed for in paragraphs (a) through (f) of the Complaint or to any relief whatsoever.

HOSPIRA'S AFFIRMATIVE DEFENSES

FIRST DEFENSE

The manufacture, use, offer for sale, sale or importation of the Hospira ANDA Product that is the subject of ANDA No. 202587 does not and will not infringe, either literally or under the doctrine of equivalents, does not and will not induce infringement of, and does not and will not contribute to the infringement of one or more claims of each of the '967, '689, RE'071 and '238 patents.

SECOND DEFENSE

The claims of each of the '967, '689, RE'071 and '238 patents are invalid under 35 U.S.C. § 102 and/or § 103 at least for the reasons stated in Hospira's Notice Letter dated February 7, 2012, cited in paragraph 15 of this Complaint.

THIRD DEFENSE

The claims of each of the '967, '689, RE'071 and '238 patents are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full

scope of the claimed invention and/or enable a person of ordinary skill in the art to use the claimed invention.

FOURTH DEFENSE

The claims of each of the '967, '689, and RE'071 patents are invalid under the doctrine of obviousness-type double patenting over U.S. Patent No. 4,537,717.

FIFTH DEFENSE

The claims of the RE'071 patent are invalid for failure to meet the requirements of 35 U.S.C. § 251 and/or 37 C.F.R. §§ 1.171-1.178.

SIXTH DEFENSE

The claims of the RE'071 patent are not infringed because the certificate of correction issued for the RE'071 patent is invalid for failure to meet the requirements of 35 U.S.C. § 255.

SEVENTH DEFENSE

To the extent the Complaint purports to allege that this case is exceptional within the meaning of 35 U.S.C. § 285 and seeks an award of attorneys fees, the Complaint fails to state a claim upon which relief can be granted.

EIGHTH DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of estoppel, waiver, and unclean hands.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Defendant and Counterclaim Plaintiff Hospira, Inc., by way of counterclaim against Plaintiff and Counterclaim Defendant Cubist Pharmaceuticals, Inc., alleges as follows:

THE PARTIES

1. Hospira is a corporation organized and existing under the laws of Delaware with its principal place of business at 275 N. Field Drive, Lake Forest, Illinois 60045.

2. On information and belief, and according to its Complaint filed in this action, Cubist is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 65 Hayden Avenue, Lexington, Massachusetts.

JURISDICTION AND VENUE

3. These counterclaims arise under the Patent Act of 1952, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.* This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

4. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

5. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.,* as amended by the Hatch-Waxman Amendments, sets forth the rules that the U.S. Food & Drug Administration ("FDA") follows when considering the approval of applications for both brand-name and generic drugs.

6. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

7. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

8. Upon approval of the NDA, the FDA publishes patent information for the

approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

9. Generic drugs are versions of brand-name prescription drugs that have been shown to be "bioequivalent" to the listed reference NDA drug approved by the FDA. *See* 21 U.S.C. § 355(j)(4)(F). Under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, *see* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e)), a generic manufacturer submits what is called an Abbreviated New Drug Application to obtain approval to sell a generic drug.

10. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of the ANDA applicant's generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

11. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product before patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

12. Hospira filed ANDA No. 202587 with the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of a generic pharmaceutical product, Daptomycin for Injection, 500 mg/vial, that is related to the daptomycin product that is the subject of NDA No. 021572 and is commercially known as CUBICIN®. Cubist is identified in FDA records as the approval holder of NDA No. 021572.

13. Hospira's ANDA No. 202587 included a "paragraph IV" certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) with respect to U.S. Patent Nos. 6,468,967 ("the '967 patent"), 6,852,689 ("the '689 patent"), RE39,071 ("the RE'071 patent"), and 8,058,238 ("the '238

patent"), among others, and alleged that the '967, '689, RE'071, and '238 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the proposed daptomycin drug product described by Hospira's ANDA No. 202587.

The '967 Patent

14. The '967 patent was issued on October 22, 2002, to Oleson and Tally and assigned to Cubist. On information and belief, Cubist is the current owner of the '967 patent, which is scheduled to expire no later than September 24, 2019.

15. Cubist listed the '967 patent in the Orange Book in connection with CUBICIN®.

16. To have the '967 patent listed in the Orange Book, the law required Cubist to certify to the FDA, under oath, that the '967 patent claims the "drug" daptomycin or a "method of using" daptomycin and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

17. By bringing suit against Hospira, Cubist has taken active steps to block Hospira's attempt to launch a generic daptomycin drug product or products.

18. The claims of the '967 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed daptomycin drug product(s).

19. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Cubist as to liability for infringement of, and validity and/or enforceability of, the '967 patent.

The '689 Patent

20. The '689 patent was issued on February 8, 2005, to Oleson and Tally and assigned to Cubist. On information and belief, Cubist is the current owner of the '689 patent,

which is scheduled to expire no later than September 24, 2019.

21. Cubist listed the '689 patent in the Orange Book in connection with CUBICIN®.

22. To have the '689 patent listed in the Orange Book, the law required Cubist to certify to the FDA, under oath, that the '689 patent claims the "drug" daptomycin or a "method of using" daptomycin and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

23. By bringing suit against Hospira, Cubist has taken active steps to block Hospira's attempt to launch a generic daptomycin drug product or products.

24. The claims of the '689 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed daptomycin drug product(s).

25. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Cubist as to liability for infringement of, and validity and/or enforceability of, the '689 patent.

The RE'071 Patent

26. The RE'071 patent was issued on April 18, 2006, to Baker et al. and assigned to Cubist. On information and belief, Cubist is the current owner of the RE'071 patent, which is scheduled to expire no later than June 15, 2016.

27. Cubist listed the RE'071 patent in the Orange Book in connection with CUBICIN®.

28. To have the RE'071 patent listed in the Orange Book, the law required Cubist to certify to the FDA, under oath, that the RE'071 patent claims the "drug" daptomycin or a "method of using" daptomycin and is a patent for which a claim of patent infringement could

reasonably be asserted against an authorized party.

29. By bringing suit against Hospira, Cubist has taken active steps to block Hospira's attempt to launch a generic daptomycin drug product or products.

30. The claims of the RE'071 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed daptomycin drug product(s).

31. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Cubist as to liability for infringement of, and validity and/or enforceability of, the RE'071 patent.

The '238 Patent

32. The '238 patent was issued on November 15, 2011, to Kelleher et al., and assigned to Cubist. On information and belief, Cubist is the current owner of the '238 patent, which is scheduled to expire no later than November 29, 2020.

33. Cubist listed the '238 patent in the Orange Book in connection with CUBICIN®.

34. To have the '238 patent listed in the Orange Book, the law required Cubist to certify to the FDA, under oath, that the '238 patent claims the "drug" daptomycin or a "method of using" daptomycin and is a patent for which a claim of patent infringement could reasonably be asserted against an authorized party.

35. By bringing suit against Hospira, Cubist has taken active steps to block Hospira's attempt to launch a generic daptomycin drug product or products.

36. The claims of the '238 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, or importation of Hospira's proposed daptomycin drug product(s).

37. Because of the foregoing facts, there is a real, substantial, immediate, and continuing justiciable controversy between Hospira and Cubist as to liability for infringement of, and as to the validity and/or enforceability of, the '238 patent.

COUNTERCLAIM I

(Declaration of Invalidity of the '967 Patent)

38. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

39. The claims of the '967 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103 for at least the reasons stated in Hospira's Notice Letter dated February 7, 2012, referenced in paragraph 15 of this Complaint.

40. Specifically, the claims of the '967 patent are invalid as anticipated and/or obvious over at least the following prior art: (1) Woodworth *et al.*, "Single-Dose Pharmacokinetics and Antibacterial Activity of Daptomycin, a New Lipopeptide Antibiotic, in Healthy Volunteers," Antimicrobial Agent and Chemotherapy 36(2):318-325 (1992) ("Woodworth"); and (2) U.S. Patent. No. 5,912,226 ("the '226 patent").

41. The claims of the '967 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103, and/or under the doctrine of obviousness-type double patenting, over U.S. Patent No. 4,537,717.

42. The claims of the '967 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

43. Hospira is entitled to a declaratory judgment that the claims of the '967 patent are invalid.

COUNTERCLAIM II

(Declaration of Invalidity of the '689 Patent)

44. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

45. The claims of the '689 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103 for at least the reasons stated in Hospira's Notice Letter dated February 7, 2012, referenced in paragraph 15 of this Complaint.

46. Specifically, the claims of the '689 patent are invalid as anticipated and/or obvious over at least the following prior art: (1) Woodworth; (2) the '226 patent; and (3) D.S. McKindley and E.G. Maderazo, "Drug Use in the Critically Ill Patient with Renal Dysfunction-Application of the DREM System," in INFECTIOUS DISEASES IN CRITICAL CARE MEDICINE BIOTECHNOLOGY OF ANTIBIOTICS, Chapter 41, 781-801 (ed. by B.A. Cunha, New York: Marcel Dekker, Inc., 1998).

47. The claims of the '689 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103, and/or under the doctrine of obviousness-type double patenting, over U.S. Patent No. 4,537,717.

48. The claims of the '689 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

49. Hospira is entitled to a declaratory judgment that the claims of the '689 patent are invalid.

COUNTERCLAIM III

(Declaration of Invalidity of the RE'071 Patent)

50. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

51. The claims of the RE'071 patent are invalid under the provisions of 35 U.S.C. § 102 and/or § 103, and/or under the doctrine of obviousness-type double patenting, over U.S. Patent No. 4,537,717.

52. The claims of the RE'071 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

53. The claims of the RE'071 patent are also invalid for failure to meet the requirements of 35 U.S.C. § 251 and/or 37 C.F.R. §§ 1.171-1.178, by recapturing during reissue subject matter that was disclaimed during prosecution of the original patent.

54. Hospira is entitled to a declaratory judgment that the claims of the RE'071 patent are invalid.

COUNTERCLAIM IV

(Declaration of Invalidity of the '238 Patent)

55. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

56. The claims of the '238 patent are invalid under one or more provisions of 35 U.S.C. §§ 102 and/or § 103 at least for the reasons stated in Hospira's Notice Letter dated February 7, 2012, cited in paragraph 15 of this Complaint.

57. Specifically, the claims of the '238 patent are invalid as anticipated and/or

obvious over at least the following prior art: (1) U.S. Patent No. 4,874,843; (2) Protein Purification: Principles, High Resolution Methods, and Applications (Janson J. and Ryden L. ed., John Wiley & Sons, Inc., 1998); (3) S-C Lin and H-J Jiang, "Recovery and Purification of the Lipopeptide Biosurfactant of Bacillus subtilis by Ultrafiltration," *Biotechnology Techniques,* 11(6): 413-416; and (4) Shaw, D.J., "Liquid-Gas and Liquid-Liquid Interfaces," Introduction to Colloid and Surface Chemistry, pp. 64-114 (Butterworth-Heinemann Ltd.).

58. The claims of the '238 patent are invalid for failing to meet the requirements of 35 U.S.C. § 112, including by failing to adequately describe the full scope of the claimed invention and/or enabling a person having ordinary skill in the art to use the claimed invention.

59. Hospira is entitled to a declaratory judgment that the claims of the '238 patent are invalid.

COUNTERCLAIM V

(Declaration of Non-Infringement of the '967 Patent)

60. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

61. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe, induce infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the '967 patent.

62. Hospira is entitled to a judicial declaration that its proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the '967 patent.

COUNTERCLAIM VI

(Declaration of Non-Infringement of the '689 Patent)

63. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

64. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe, induce infringement of, or contribute to the infringement of, any valid and/or enforceable claim of the of the '689 patent.

65. Hospira is entitled to a judicial declaration that its proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the '689 patent.

COUNTERCLAIM VII

(Declaration of Non-Infringement of the RE'071 Patent)

66. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

67. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the of the RE'071 patent.

68. The claims of the RE'071 patent are not infringed because the certificate of correction issued for the RE'071 patent is invalid for failure to meet the requirements of 35 U.S.C. § 255.

69. Hospira is entitled to a judicial declaration that its proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim

of the RE'071 patent.

COUNTERCLAIM VIII

(Declaration of Non-Infringement of the '238 Patent)

70. Hospira realleges and incorporates by reference the allegations contained in the previous paragraphs of the Counterclaims as if set forth here.

71. The manufacture, use, sale, offer for sale, or importation into the U.S. of Hospira's proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the of the '238 patent.

72. Hospira is entitled to a judicial declaration that its proposed daptomycin products that are the subject of ANDA No. 202587 would not infringe any valid and/or enforceable claim of the '238 patent.

HOSPIRA'S PRAYER FOR RELIEF

WHEREFORE, Hospira, Inc. respectfully prays that the Court grant the following relief:

A. Declaring that Hospira's proposed Daptomycin for Injection (500 mg/ vial) product does not, and would not if commercially manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid and enforceable claim of U.S. Patent Nos. 6,468,967, 6,852,689, RE39,071 and 8,058,238;

B. Declaring that Hospira, Inc. has not infringed, contributed to the infringement of, and/or induced the infringement of any valid and enforceable claim of U.S. Patent Nos. 6,468,967, 6,852,689, RE39,071 and 8,058,238 and is not liable for infringement;

C. Declaring that the claims of U.S. Patent Nos. 6,468,967, 6,852,689, RE39,071 and 8,058,238 are invalid;

D. Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding to Hospira attorneys' fees and expenses in this action;

E. Awarding Hospira costs; and

F. Awarding Hospira such other and further relief as the Court may deem just, proper and equitable under the circumstances.

Dated: May 16, 2012

PHILLIPS, GOLDMAN & SPENCE, P.A.

By: */s/ John C. Phillips, Jr.*

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